Perspectives on an alternative career path in regulatory science

F. Owen Fields
Pfizer, Worldwide Research and Development, Collegeville, PA 19426

ABSTRACT **Perspectives are provided on an alternative career path in regulatory science for those currently involved in basic biology research. This path is compared and contrasted with basic research, and factors to be examined if one is considering such a path are discussed.**

Monitoring Editor
William Bement
University of Wisconsin

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INTRODUCTION

My goal in this article is to provide some perspective to those currently involved in basic biological research on an alternative career path that others and I have chosen. I relate this perspective as a former basic scientist. That is, I was where the typical readers of *Molecular Biology of the Cell* now are. Having been you and having known many people in your position, I know that some of you are considering alternative career paths for a wide range of reasons.

I begin with a few relevant facts of my biography. I attended college at a medium-sized school in my hometown of Wichita, Kansas, in engineering and business. I quickly felt the need to get my head out of the weeds, however, and switched to a major in biochemistry. After this, I pursued my PhD at the University of California, Berkeley, where my graduate advisor was Jeremy Thorner. By the time I was finishing up my thesis research and was beginning to think of what direction my career should take, I realized a couple of things. First, I wanted to at least try something away from the bench. Second, I had always been interested in the interface between science and society and specifically in science-related policy. I had no idea, however, how to pursue such a career interest.

At about this time I was at a conference and cutting through a job fair on my way from one scientific session to another and noted a person from the U.S. Food and Drug Administration (FDA) sitting behind an FDA banner at a table. She was recruiting but seemed rather lonely. I initially walked past, but then turned around and sat down, and we talked. She informed me that the FDA was wrestling with how to regulate food biotechnology and needed to hire some molecular biologists. To make a long story short, I decided to take the job and moved to Washington, DC, where I initially worked just off the National Mall before my office moved downtown, north of the White House. There I helped develop U.S. food biotechnology policy, and I wrote the U.S. approval decision for a number of products, including the so-called "Round-up Ready" soybean.

Not long thereafter, the approval system was becoming well-trodden ground, and I decided to move to pharmaceutical research. I started at Wyeth Research, outside of Philadelphia. There I worked on a number of programs, including BMP2, a program I am proud to say won the Prix Galien Award for biotherapeutics in 2008, and many other programs. After some years, as happens in this business, Wyeth became part of another corporation through a merger, in this case Pfizer. Initially I was in charge of regulatory strategy for the Pfizer Biotherapeutics Research Unit, and thereafter I took on responsibility for all of the new drugs in Pfizer's worldwide research and development organization.

WHAT I CONSIDERED BEFORE I MADE "THE JUMP"

When I made what I now call "The Jump" out of basic research, I wondered about a number of matters, and over the past 22 years I have reconsidered these matters periodically. It occurred to me that anyone at the point I once was would likely consider the same matters, so I address these in the rough sequence in which they occurred to me.

What do you actually do in this role?

This is perhaps the hardest question to answer. New drug development is among the hardest things to do in the realm of human accomplishment. One of the reasons it is so complex is that (appropriately) it is one of the most regulated activities one can engage in; the level of regulation is higher than in any other industry besides, perhaps, the nuclear power and weapons industries. Scientific teams

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Address correspondence to: F. Owen Fields (owen.fields@pfizer.com).

that accomplish successful new drug development are very large and complicated, and it is your job as the regulatory scientist to lead them through the regulatory science requirements. I use the term "regulatory science" because, in contrast to some other fields, in this industry all of the requirements are driven by scientific considerations. Communication (making it clear to regulatory agencies what you are doing, and why, in what is essentially a massive peer review process) is also an important part of the role.

How does it compare with doing basic science?
Drug development, and especially the regulatory science aspects of drug development, are more analogous to so-called "Big Science." A drug entering early-stage clinical development has been touched by literally hundreds of people, and the cost of discovering it, manufacturing it, and even conducting the smallest of clinical trials is several times as expensive as a typical yearly laboratory budget in basic biology. By the time it is subject to the approval process, thousands of scientists have touched it, and the level of investment required is unimaginable, unless you run a small country.

What is "the jump" like?
The transition out of basic science can be disorienting to some, and it requires mental plasticity as you go from a role in which you know more about your research than anyone else in the world to a role in which there is a truly vast amount to learn and no mechanism for learning it other than jumping in, getting mentored, and self-teaching. In addition, basic science is all about pure scientific reality, whereas regulatory science is an agglomeration of norms and paradigms that, although science based, have been built up by sometimes random accretion over the past century.

Is a background in basic science useful in this area—will my knowledge and skills be used?
Yes, very much so, in terms of the fundamental skills required in basic biology. The reason is simple: as with basic science, the amount of information required to pass regulatory science hurdles is vast, and if you get your head in the weeds, you will simply get lost. It is also the case that in this area of endeavor the fundamental question is always, "OK, these are the facts, now what does all this actually mean in the big picture, and what then must we do?" Having said this, much of the highly detailed information in your head will atrophy as it is replaced by other things. The important concepts you learned as a scientist will remain fresh in your mind.

Are the people as intellectually talented and creative as the people in fundamental research?
The consistency of intellectual talents of people working in basic research, at least in the environment in which I worked at Berkeley, is very high. The level of talent in this area is not as consistent. However, in this role you do work with tremendously smart and knowledgeable people, including basic scientists involved in discovery and research, as well as physicians, and they can often teach you as much about your work as you can teach them about theirs.

How does one get into such role?
Historically there were no certification or master's programs. There now are a few around the country, and they can be a useful way to enter the field. However, many people still enter the field from either some other area of pharmaceutical research or academia, and there is no typical path. I seem to represent the rare case of someone entering the field immediately after graduate school. Others enter pharmaceutical research in some manner and then transition to the role. Others were unemployed or underemployed and happened to stumble across the role. In my experience, a minority enter the field by actual design (i.e., they decide they are interested and actively seek such a role), but many discover the nature of the role by working with a regulatory scientist and gain interest in that manner.

SOME EXAMPLE CAREER PATHS

In preparing this article, I thought that some examples of actual career paths would be useful, and I took an admittedly unscientific survey of a series of selected colleagues in regulatory science at Pfizer. The paths of those I polled are noted here, as well as some high-level perspective from these individuals. I have left them anonymous.

Person 1
Parent was in the industry, and therefore this person knew about the role early; attended graduate school; entered industry as a scientific writer, then moved to regulatory science. Relevant quote: "The analytical thinking, scientific writing, and communication skills learned serve as a strong foundation. … Feel like I've had a greater impact on patients. … The ability to interact with all facets of the company … and health authorities … makes the job continually 'fresh' and intellectually stimulating."

Person 2
Completed graduate school, took a postdoctoral role in academia, entered a research role in start-up company, and then moved into regulatory science. Relevant quote: "Having a broad scientific background was really useful … but I use my scientific background less now for day to day work … but if I didn't have it, I would probably feel lost when listening to program scientific discussions. I think my impact has been much greater than if I had stayed in academia and focused on basic science."

Person 3
Completed graduate school, took an academic postdoctoral role, then faculty role in academia, followed by a laboratory head role in industry, then moved into regulatory science. Relevant quote: "I think academic research might have been more intellectually challenging in delving in depth into scientific problems, but regulatory science and strategy requires a breadth of skill sets on multiple levels from the integration of multiple scientific disciplines."

Person 4
Completed graduate school, then moved to a regulatory consultancy, followed by a regulatory science role in industry. Relevant quote: "I knew in my final year of the PhD that a career in the laboratory was not for me as my desire was to have a broader interface with different aspects of science and drug development. … I found out that roles in regulatory science required all the transferable skills which you gain in graduate school. … I believe that it was a good career choice for me and would have liked to have known about this career route at an earlier point in time."

Person 5
Completed graduate school, took an academic postdoctoral role, then spent 3 years in research at small biotech, worked 12 years in R&D at a large Pharma, was laid off, and then moved into regulatory science after completing a master's program. Relevant quote: "I wanted to change career path from 'great expertise in a narrow area' to 'big picture' view. A background in science is still of great value to me today; however most of the exact science that I did is

irrelevant. I would consider regulatory to be equally intellectually challenging as academic science, but in a different way. Unlike basic science, in regulatory one does not generally choose the problem one wants to tackle. Rather, the problems come to you, frequently unexpectedly, and may require integrating knowledge across highly divergent areas (science, law, etc.). I wish I would have moved earlier."

Person 6

Attended medical school and a medical fellowship in academia, then worked on a National Cancer Institute fellowship, served as a medical reviewer at FDA, and then moved to a regulatory role in industry. Relevant quote: "All these experiences gave me an appreciation for the need for new treatments and the potential impact on multiple patients that participation in the development process can bring. … I could be more heavily involved in decision making about the practicalities of program planning and execution in a global environment that integrates business, clinical, and other considerations on an ongoing basis."

CONCLUSION

Many of the readers of this article, by either choice or necessity, will either seek, or be forced by circumstance, to pursue an alternative career outside of basic research. I have attempted to give some perspective on one such path. I hope this perspective is useful to the reader.